

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 May 2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5, 6, and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Padgett (US 4,644,586) or Trewella et al. (US 3,073,507).

Padgett teaches a bag **10** having a first porous section **14** and a second non-porous section **12**, the two sections in registry with each other. The porous section may be a nonwoven (col.2, lines 55-57) and the non-porous section may be an SMS polypropylene (polyolefin) laminate having a barrier coating applied thereto (col.3, lines 19-22). After sterilization (steam or ETO), the contents **28** of the bag are moved to the second non-porous section **12** and bag is sealed **38** adjacent the interface between the

first and second portions to create a sealed, sterile portion. See col.4, lines 10-38; Figures 4-6.

Trewella et al. teaches a bag **10** having a first porous section **13** and a second non-porous section **11**. The porous section of the bag may be paper (nonwoven) and the nonporous section may be a film of polyethylene, a polyolefin. See col.3, lines 14 and 50-64. After steam sterilization the bag may be sealed at an interface **21** between the first and second sections. See Figures 6 and 10; col.4, line 71 to col.5, line 15. The intended use of the device does not structurally limit the bag in any patentable sense.

As to the recitation of the contents of the bag, it has been held that "expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." See *In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Furthermore, as to the contents and the second section being under a vacuum or positive pressure, these limitations are directed to the ultimate intended use of the device and do not limit the bag in any structural manner.

As to claims 5 and 6 and the limitations wherein "the bag and its contents being under a slight vacuum" and "the bag and its contents being under a slight positive pressure" are not considered to be structurally limiting on the bag but are intended uses of the bag.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 7, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trewella et al. in view of McDonald (US 6,030,578).

Trewella et al. is silent with respect to a closed collar or port attached to the non-porous section. McDonald, however, discloses a container **201** for sterilizing and transferring articles to a sterile enclosure. The container includes a collar **202** for attachment to a sterile enclosure during transferring of the sterilized articles. This collar is certainly capable of use as a pressure or vacuum port, as well. Since the bag of Trewella et al. is disclosed for use in the sterilization of medical articles, it would have been obvious to use the bag of Trewella et al. in the sterile environment of McDonald and when doing so, to provide a collar for connection to the enclosure.

6. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Padgett or Trewella et al., both in view of Reyner (US 4,436,203).

Padgett teaches a bag **10** having a first porous section **14** and a second non-porous section **12**, the two sections in registry with each other. The porous section may be a nonwoven (col.2, lines 55-57) and the non-porous section may be an SMS polypropylene (polyolefin) laminate having a barrier coating applied thereto (col.3, lines

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19-22). After sterilization (steam or ETO), the contents **28** of the bag are moved to the second non-porous section **12** and bag is sealed **38** adjacent the interface between the first and second portions to create a sealed, sterile portion. See col.4, lines 10-38; Figures 4-6.

Trewella et al. teaches a bag **10** having a first porous section **13** and a second non-porous section **11**. The porous section of the bag may be paper (nonwoven) and the nonporous section may be a film of polyethylene, a polyolefin. See col.3, lines 14 and 50-64. After steam sterilization the bag may be sealed at an interface **21** between the first and second sections. See Figures 6 and 10; col.4, line 71 to col.5, line 15.

Neither Padgett nor Trewella et al. disclose a step of applying a vacuum or a positive pressure to the second section during or after the formation of the second seal. Reyner teaches that it was known in the art at the time of the invention to seal a container **7** under a slight vacuum in order to indicate container integrity, wherein tampering of the container causes the pressure within the container to rise. See col.3, lines 14-18; col.6, lines 30-36 and lines 51-52. The container is a flexible enclosure (col.3, lines 10-14) and may be sterilized (col.6, lines 27-29). As packaging articles under a slight vacuum is evidenced by Reyner to permit a visual indication of the integrity of the package and thus, whether the package contents remain in a sterile condition, it would have been obvious to the sealing method of Reyner in the methods of Padgett and Trewalla et al..

Response to Arguments

7. Applicant's arguments filed 6 May 2008 have been fully considered but they are not persuasive.
8. Applicant argues that neither Padgett nor Trewella et al. disclose maintaining the second section in a condition of a vacuum or positive pressure. The Examiner maintains that this type of limitation is no more than an intended use of the bag and does not structurally limit the *bag* from the bags of Padgett and Trewella et al.. The bags of the prior art are certainly capable of being in a condition of a slight vacuum or a slight pressure. In fact, Applicant seems to be arguing the limitations of the article of manufacture as illustrated in Figure 2 of the instant invention. If Applicant intends to claim the sealed transfer bag *in combination with* the sterilized articles located therein, wherein the sealed transfer bag is under pressure or vacuum, then the article of manufacture itself should be claimed. As it stands, the instant claims are either article claims drawn to a bag or a process of using the bag.

Certainly it is not patentable to merely pressurize or depressurize the bag of the prior art as this is an ultimate use of the bag itself, not a limitation directed to the structure of the bag. According to Applicant's standard, it would be patentable to take a known Ziplock™ bag, fill it with air, and zip it closed. Clearly, this would not be a patentable invention.
9. As to MacDonald, Applicant argues that one of ordinary skill in the art would not have thought to use the collar of MacDonald to form a vacuum or pressure port since MacDonald is at atmospheric pressure. However, Applicant appears to be reading

structure into the term 'vacuum or pressure port' which is simply not in the claims. All that is required by the term 'vacuum or pressure port' is a port that *is capable* of being put into communication with a vacuum or pressure. The apparatus claims do not require a source of vacuum or pressure. The port of MacDonald is capable of being put into communication with a vacuum or pressure and Applicant has failed to show that it cannot be. Moreover, the combination with MacDonald results in using the port of MacDonald as a transfer port in the manner disclosed by MacDonald. The port of the combination is not used in connection with a source of vacuum or pressure, not do the claims require such.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is (571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

elm
8 June 2008